PTO/SB/01A (08-03) Approved for use through 06/30/2006. OMB 0651-0032

AUG 2 3 2004 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE of 1995, no persons are required to respond to a collection of information unless if displays a valid OMB control number.

### DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN **APPLICATION DATA SHEET (37 CFR 1.76)**

Vaginal or Rectal Applicator

Title of Invention

| As the below named inventor(s), I/we declare that:  |  |  |  |  |  |
|---|--|--|--|--|--|
| This declaration is directed to:  |  |  |  |  |  |
| The attached application, or  |  |  |  |  |  |
| Application No. 10/759,695 , filed on January 16, 2004 ,  |  |  |  |  |  |
| as amended on(if applicable);   |  |  |  |  |  |
| I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;   |  |  |  |  |  |
| I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;   |  |  |  |  |  |
| I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application. |  |  |  |  |  |
| All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.                 |  |  |  |  |  |
|   |  |  |  |  |  |
| FULL NAME OF INVENTOR(S)  |  |  |  |  |  |
| Inventor one Gerianne Tringali DiPiano  |  |  |  |  |  |
| Signature Citizen of: USA   |  |  |  |  |  |
| Inventor two. John Andrew Ziemniak  |  |  |  |  |  |
| Signature:Citizen of: USA   |  |  |  |  |  |
| Inventor three: Joel Martin Bartholomew   |  |  |  |  |  |
| Signature:Citizen of: USA   |  |  |  |  |  |
| Inventor four:  |  |  |  |  |  |
| Signature:Citizen of:   |  |  |  |  |  |
| Additional inventors or a legal representative are being named onadditional form(s) attached hereto.  |  |  |  |  |  |

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

AU6 2 3 2004

Title of Invention

PTO/SB/01A (08-03)

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## DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN .APPLICATION DATA SHEET (37 CFR 1.76)

Vaginal or Rectal Applicator

| As the below harned invento  | r(s), I/we declare that:  |                        |                    |   |  |  |
|--|---|------------------------|--------------------|---|--|--|
| This declaration is directed to:   |   |                        |                    |   |  |  |
| The attached application, or   |   |                        |                    |   |  |  |
| V  | Application No  | 10/759,695             | , filed on         | January 16, 2004                          |  |  |
|  | as amended on   | l                      |                    | (if applicable);                          |  |  |
| I/we believe that I/we am/are sought;  | e the original and first  | inventor(s) of the s   | ubject matter wh   | nich is claimed and for which a patent is |  |  |
| I/we have reviewed and und amendment specifically refer  | lerstand the contents or<br>rred to above;  | of the above-identifi  | ed application, in | ncluding the claims, as amended by any    |  |  |
| material to patentability as o<br>became available between   | I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application. |                        |                    |   |  |  |
| All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.  |   |                        |                    |   |  |  |
| · · · · · · · · · · · · · · · · · · ·  |   |                        |                    |   |  |  |
| ELLI NANE OF INVENTOR  | VC)   |                        |                    |   |  |  |
| FULL NAME OF INVENTOR  | , ,   |                        |                    |   |  |  |
| FULL NAME OF INVENTOR Inventor one:  Signature:  | , ,   | Citizen of: _          | USA                |   |  |  |
| Inventor one: Gerianne T   | , ,   | Citizen of: _          | USA                |   |  |  |
| Inventor one: Gerianne T   | Pew Ziemniak  | 1                      |                    |   |  |  |
| Inventor one: Gerianne T   | Fringali DiPiano  Pew Ziemniak  Memnud  | 1                      |                    |   |  |  |
| Inventor one: Gerianne Telegrature: Signature: John And Constant C | Fringali DiPiano  Pew Ziemniak  Memnud  | Citizen of:            | USA                |   |  |  |
| Inventor one: Gerianne Televisione Inventor one: Signature: Signature: John And Signature: Joel Martinature: Gerianne Televisione Inventor three: Joel Martinature:  | Fringali DiPiano  ew Ziemniak  Lemniak  Bartholomew   | Citizen of:Citizen of: | USA                |   |  |  |
| Inventor one: Gerianne Telegrature:  Inventor two: John And John A | Fringali DiPiano  ew Ziemniak  Monned  Bartholomew  | Citizen of:Citizen of: | USA                |   |  |  |

(and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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U.S. Patent Output

U.S. Patent

## ÉDÉCLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

AUG 2 3 200

| Title of Invention  | Vaginal or Rectal Applicator  |  |  |  |
|---|---|--|--|--|
| As the below named inventor(s), I/we declare that:  |   |  |  |  |
| This declaration is directed to:  |   |  |  |  |
|   | The attached application, or  |  |  |  |
|   | Application No10/759,695, filed onJanuary 16, 2004,   |  |  |  |
|   | as amended on(if applicable);   |  |  |  |
| I/we believe that I/we sought;  | e am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is  |  |  |  |
|   | and understand the contents of the above-identified application, including the claims, as amended by any ally referred to above;  |  |  |  |
| material to patentab<br>became available b  | I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application. |  |  |  |
| All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon. |   |  |  |  |
| FULL NAME OF IND  | ENTOR(s)  |  |  |  |
| FULL NAME OF INV  | ianne Tringali DiPiano  |  |  |  |
|   |   |  |  |  |
|   | Citizen of: USA   |  |  |  |
| Inventor two:John   | n Andrew Ziemniak   |  |  |  |
| Signature:  | Citizen of: USA   |  |  |  |
| Inventor three: Joel Martin Bartholomew   |   |  |  |  |
| Signature:  | Bankolonew Citizen of: USA  |  |  |  |
| Inventor four:  |   |  |  |  |
| Signature:  | Citizen of:   |  |  |  |
|   | stors or a legal representative are being named onadditional form(s) attached hereto.   |  |  |  |

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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|-----------------|----------|---|-------|
| Application Nu  | nber     | 10/759,695  |       |
| Filing Date     |          | January 16, 2004                                  |       |
| First Named Inv | rentor   | Gerianne Tringali DiPiano                         |       |
| Title           |          | Vaginal or Rectal Applicator                      |       |
| Art Unit        |          |   |       |
| Examiner Name   | ,        |   |       |
| Attorney Docke  | t Number | FEM 105   |       |

| Lhoroby appoint:  | <u> </u>  |   |                 |                          |   |
|---|---|---|-----------------|--------------------------|---|
| I hereby appoint:   | . Г   |   |                 |                          | ¬ · ·                                   |
| Practitioners associated  | with the Customer Number:   |   | 235             | 79                       |   |
| OR  | , <u>L</u>  |   |                 | ·                        |   |
| Practitioner(s) named be  | low:  | •<br>•                                  |                 | •                        |   |
|   | Name ·-   | • | ٠.              | Registration I           | Number                                  |
| Patrea L. Pabst   |   | 31,2                                    | 84              | -                        |   |
| Rivka D. Monheit  |   | 48,7                                    | 31              |                          |   |
| Todd S. Hofmeister  |   | . 53,02                                 | 29              |                          |   |
|   |   |   |                 |                          |   |
| as my/our attorney(s) or agent(<br>Trademark Office connected th  | s) to prosecute the application is  | dentified above,                        | and to tra      | ansact all business i    | n the United States Patent and          |
| The address associate OR The address associate OR Firm or Individual Name Address Address City Country  | Patrea L. Pabst, Reg. No. Suite 2000, One Atlantic 1201 West Peachtree Stre Atlanta USA | 2<br>2<br>31,284; Holla<br>Center       | 23579<br>nd & K | night LLP                | Zip   30309-3400                        |
| Telephone   | (404) 817-8473  |   | Fax             | (404) 817-8588           |   |
| I am the: Applicant/Inventor.  Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) |   |   |                 |                          |   |
|   | SIGNATURE of  | Applicant or Ass                        | signee o        | f Record                 |   |
| Name Serianne   | ringali DiPiano   | On b                                    | ehalf of F      | emmePharma, Inc.         | A 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 |
| Signature / www.  | ingele Delaro   |   |                 |                          |   |
| Date (( ) 5/2/  | syD   |   |                 | Telephone 6              | doi 995-0801                            |
| NOTE: Signatures of all the inventor forms if more than one signature is  | rs or assignees of record of the entirequired, see below*.                              | e interest or their re                  | epresenta       | tive(s) are required. Su | bmit multiple                           |
| *Total of   | forms are submitted.  |   |                 |                          |   |

This collection of information is required by 37 CFR 1.31 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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STATEMENT UNDER 37 CFR 3.73(b) Applicant/Patent Owner: Gerianne Tringali DiPiano, John Andrew Ziemniak, and Joel Martin Bartholomew Application No./Patent No.: 10/759,695 Filed/Issue Date: January 16, 2004 Entitled: Vaginal or Rectal Applicator FemmePharma, Inc. corporation of the Commonwealth of Pennsylvania (Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.) states that it is: 1. The assignee of the entire right, title, and interest; or 2. an assignee of less than the entire right, title and interest. The extent (by percentage) of its ownership interest is in the patent application/patent identified above by virtue of either: A. [r] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel Frame , or for which a copy thereof is OR B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below: ----- To: -The document was recorded in the United States Patent and Trademark Office at \_\_\_\_, or for which a copy thereof is attached. Reel \_\_\_\_\_, Frame \_\_\_\_ 2. From: To: The document was recorded in the United States Patent and Trademark Office at \_\_\_\_, or for which a copy thereof is attached. 3. From: To: The document was recorded in the United States Patent and Trademark Office at \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached. [ ] Additional documents in the chain of title are listed on a supplemental sheet. [ ] Copies of assignments or other documents in the chain of title are attached. [NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08] The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee 610: 995.0801 XI Telephone number

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

#### ASSIGNMENT

We, Gerianne Tringali DiPiano of 2065 General Alexander Drive, Malvern, Pennsylvania 19355; John Andrew Ziemniak of 715 Evans Road, Gwynedd Valley, Pennsylvania 19437; and Joel Martin Bartholomew of 1095 North Road, Danielsville, Pennsylvania 18038, in consideration of ten dollars and other valuable consideration paid to us by FemmePharma, Inc., a corporation of the Commonwealth of Pennsylvania, having its principal place of business at 37 West Avenue, Wayne, Pennsylvania 19087 (hereinafter "said Assignee"), the receipt of which is hereby acknowledged, do hereby sell, assign and transfer unto said Assignee, its successors and assigns, the entire interest for the United States of America, and its territories and all foreign countries and jurisdictions, including all rights of priority under the International Convention for the Protection of Industrial Property, in a certain invention or improvement in "Vaginal or Rectal Applicator" described in U.S. Serial No. 10/759,695 filed in the United States Patent and Trademark Office on January 16, 2004 by Gerianne Tringali DiPiano, John Andrew Ziemniak, and Joel Martin Bartholomew, and in the provisional application to which priority is claimed, being U.S. Provisional Application Serial No. 60/441,033 filed in the United States Patent and Trademark Office on January 16, 2003, and in all Letters Patent of the United States and its territories and all foreign countries and jurisdictions which may or shall be granted on said invention, or any parts thereof, or on said application, or any provisional, divisional, continuation, continuation-in-part, reissue, or other applications based in whole or in part thereon. And we agree, for ourselves and our executors and administrators, with said Assignee and its successors and assigns, but at its or their expense or charges, hereafter to execute all applications, amended specifications, deeds or other instruments, and to do all acts necessary or proper to secure the grant of Letters Patent in the United States and its territories and in all other foreign countries and jurisdictions to said Assignee, with specifications and claims in such form as shall be approved by the counsel of said Assignee, and to vest and confirm in said Assignee, its successors and assigns, the legal title to all such patents.

Title: "Vaginal or Rectal Applicator

By: Gerianne Tringali DiPiano, John Andrew Ziemniak, and Joel Martin Bartholomew

Filed: January 16, 2004

ASSIGNMENT

And we do hereby authorize and request the Commissioner of Patents and Trademarks of the United States to issue such Letters Patent as shall be granted upon said application or applications based thereon to said Assignee, its successors and assigns.

| WITNESS my hand and            | l seal this $30$            | day of _       | Que                                    | , 2004.  |
|--------------------------------|-----------------------------|----------------|--|--|
|                                |                             |                |  |  |
|                                |                             | Mian G         | we Swal .<br>Gerianne Tringali DiPi    | Main   |
|                                |                             |                | ************************************** | MILV   |
| Commonwealth of Pennsylvani    | ia )                        |                |  |  |
| County of Sugare               |                             |                |  |  |
| acknowledged the foregoing ins | strument to be h<br>, 2004. | ier free act : | and deed, before me                    | this <u>30</u>   |
|                                |                             | Revin          | M Sondik<br>Notary Public              |  |
| My Commission expires:         |                             |                | COMMONWEALT                            | H OF PENNSYLVANIA  |
| Wiy Commission Capitos.        |                             |                |  | arial Seal   |
|                                |                             |                | Kevin M. Gond<br>Radnor Twp.,          | dek, Notary Public Delaware County Expires June 10, 2007 |

2

Member, Pennsylvania Association Of Notaries

Title: "Vaginal or Rectal Applicator
By: Gerianne Tringali DiPiano, John Andrew Ziemniak, and Joel Martin Bartholomew
Filed: January 16, 2004
ASSIGNMENT -

| WITNESS my hand and seal this Ond day of July , 2004.   |
|---|
| John Andrew Zjemniak  |
|   |
| Commonwealth of Pennsylvania  |
| County of Montgomory  |
| Then personally appeared the above named John Andrew Ziemniak and   |
| day of 1004.  |
| , 2004.   |
| San Jan-  |
| My Commission expires Jan. 31, 2005  NOTARIAL SEAL LISA GILPIN, Notary Public  Notary Public  Notary Public |

Title: "Vaginal or Rectal Applicator

By: Gerianne Tringali DiPiano, John Andrew Ziemniak, and Joel Martin Bartholomew

Filed: January 16, 2004 ASSIGNMENT

| WITNESS my hand and seal this _\frac{1}{t}                | day of June, 200                          | 04.       |
|---|---|-----------|
|   | Joel Martin Bartholomew                   | <u></u> - |
| Commonwealth of Pennsylvania ) County of LUNGO            |   |           |
| Then personally appeared the above n                      | <i>c</i> <b>!</b> -                       |           |
| acknowledged the foregoing instrument to be day of, 2004. | his free act and deed, before me this 15+ |           |
|   | Andua M. Kun Kel. Notary Public           |           |
| My Commission expires: <u>Stpt. 10<sup>th</sup>, 2(1)</u> | Dlo                                       |           |

COMMONWEALTH OF PENNSYLVANIA

Notarial Seal
Andrea M. Kunkel, Notary Public
City of Allentown, Lehigh County
My Commission Expires Sept. 10, 2006

Member, Pennsylvania Association of Notaries

# 1578255\_v1